

**REMARKS**

Claims 1-10, 14-33 and 36-42 were pending prior to this reply and amendment. New Claims 43 and 44 are added herein. Thus, Claims 1-10, 14-33 and 36-44 are currently pending. Reconsideration of the application is respectfully requested.

Claims 1-10, 14-33 and 36-39 currently stand rejected per the December 29, 2008 Office Action. For reasons indicated below, applicant traverses the rejections, and requests reconsideration of the application and allowance of the pending claims.

**Claims 1-4, 6-10, 16, 19-23 and 40-41 are not rendered obvious by the teachings of WO 98/30262 to Dmitrovic et al.**

Applicant respectfully disagrees with the examiner's position that Claims 1-4, 6-10, 16, 19-23 and 40-41 would have been obvious to one of ordinary skill under 35 U.S.C. § 103(a), in light of the teachings of WO 98/30262 to Dmitrovic et al. (hereinafter "Dmitrovic"), and requests reconsideration of these claims, and withdrawal of the rejection.

Dmitrovic describes an inhalation device from which metered doses of medicament in the form of a powder can be dispersed to a user. A first embodiment is described with reference to Figs 1-5. This involves a powder inhaler having a main body portion (5) defining a powder reservoir (6). The lower end of the reservoir (6) defines an aperture (11), that opens into a dosing recess (22) formed in a dosing member (3) that rests below the reservoir. The dosing member (3) is a portion of a rotatable lower body portion (9). The lower body portion (9) is pivotally connected to the main body portion (5). The interface between the bottom of the reservoir (6) and the top of the dosing member (3) is configured to create a dynamic seal, as discussed at page 6, line 20- page 9, line 2.

The main body portion has a further aperture (8) that extends into a mouthpiece (7). The dosing recess (22) formed in the dosing member (3) is designed to first be in

communication with the powder reservoir 6, and is pivotally moved upon pivotal rotation of the lower body portion (9) to be in communication with aperture (8) leading to the mouthpiece. In this way, the dose contained in the metering recess may be transferred to a patient.

To allow transfer of a dose of powder from the reservoir to the mouthpiece, aperture (11) is radially offset by an angle of 90° about the vertical axis of the device from the aperture (8) at the inner end of the mouthpiece. Rotation of the lower body portion (9) by 90° moves the dosing receptacle from aperture (11) to the mouthpiece aperture (8). This rotation though also allows the mouthpiece cover, once disengaged from the main body portion, to be rotated away from the mouthpiece around pivot (34), allowing for easy access to the mouthpiece.

Similarly, in a second embodiment described in Dmitrovic, shown in Figures 6 to 9, the device dust cover (63) is rotatable about a first axis defined by a pivot (64). In operation, the user opens the dust cover (63) on pivot (64). The lower body portion (69) is then rotated 90 degrees about central axis X-X, which causes the inner components, namely the recess (65) in the dosing member (53), to move from a filling position where the recess (65) is in communication with an outlet (51) of a powder reservoir (56), to an emptying position, where the dosing recess is in communication with an air flow path and a mouthpiece (57). The second embodiment involves a dose indicator, which operates via rotation of the lower body portion. As described on page 11, line 7 to page 13, line 4, the dose indicator operates when the lower body portion is rotated from a "stop point", where the recess (65) was aligned with the aperture (65) leading to the mouthpiece (57)—i.e., after the user accessed the dose through the mouthpiece. Thus the stop point acts as a sign to the user that the dose is positioned for use, and also marks the start point for the return rotation wherein the ratchet initiates operation of the indicator that registers that a dose has been delivered. The indicator, shown in Figure 9, is a threaded shaft (70), that causes a captive indicator nut (77) to travel a set amount. (page 11, lines 7 -16). The pitch of the thread and the number of teeth on sprocket 72 are selected to ensure that the dose indicator nut travels from the uppermost "full" position to the lowermost "empty" position when the device has been used sufficiently to deliver its prescribed number of doses, so indicating to the user that the device is empty.

Dmitrovic does not describe the invention of claim 1. In particular, it fails to describe a device "wherein the first and second parts are pivotally connected so that the first part is pivotable to different angular positions with respect to the second part when the container is in the open state **including a first angular position where the first part is disposed behind the second part** and **wherein, when the first part is in the first angular position, the first and second parts are movable to a nesting state where the first part and the second part nest together with the first part encapsulating a substantial portion of the second part, but with the container still in the open state.**"

None of the figures in Dmitrovic depict a state where the mouthpiece cover is moved behind the main body of the device. While, Dmitrovic does point out that "it will be appreciated that this angle [the angle between the reservoir aperture (11/51) and mouthpiece aperture (8/66)] can be substantially increased or slightly decreased according to the desired angle of rotation of the dust cover, lower body portion and dosing member. (page 9, line 24- page 10, line 2)", one of ordinary skill would not be motivated to undertake the change in rotation of 180 degrees suggested by the examiner, as this would greatly increase the wear on the dynamic seal operating between the lower surface of the reservoir/main body portion (5/55) and the upper surface of the dosing member (3/53). The increased rotation could thus increase the risk of failure of the seal and subsequently, increase the chances that moisture would leak into the interior of the cavity. As this device is intended for delivery of a pharmaceutical, moisture ingress increases that risk of chemical degradation of drug product as a result of chemical change. Further, moisture ingress is also known to be associated with change in physical change, for example a change in the fine particle fraction of the dry powder formulation delivered in the device over time. As particles deposit in the lung based on their aerodynamic particle size, and as moisture is known to cause an increase in aggregation behavior of particles, the risk of particles increasing in size beyond what is considered to be a "respirable size" increases with levels of humidity. The result of this is that the amount of active component in the dose delivered to the patient is actually decreased as a result of particle aggregation, as particles which are agglomerated to a non-respirable size will not reach the originally targeted regions in the inhalation tract.

One of ordinary skill would also be disinclined to move the rotational position of the dust cover in Dmitrovic in the manner claimed in claim 1, as it would negatively impact the operation of the dose indicator described in the Figure 6-9 embodiments. As mentioned above, the dose indicator operates on the return rotation of the mouthpiece from the "open position" to the "closed" position. This return stroke which indicates use is doubled as one moves from the 90 degrees of rotation depicted in Dmitrovic, to one where the mouthpiece is behind the main body. The change suggested by the examiner would thus increase by 100% the amount of travel that would need to be accommodated by the threaded shaft (70) and indicator nut (77). To accommodate this would mean doubling the threading/ halving pitch of the shaft and correspondingly and needlessly adding either to the length of a shaft. Increasing shaft length is undesirable as it would likely increase cost of goods, but also entail taking up more space in a hand held device where such space is at a premium. The doubling the threading of the shaft and nut on the other hand decreases the amount of material between threads on the nut, possibly weakening the integrity of the of the indicator nut, and thus increasing the risk of the device mis-registering the amount of drug delivered or remaining in the device.

Dmitrovic also does not disclose or suggest that the mouthpiece can be flipped up, so as to nest over the main body portion of the depicted device, nor that the nested portion would encapsulate *a substantial portion* of the main body portion, so as to render Claim 1 obvious.

Dmitrovic describes a mouthpiece that when the device is in its open state with the dose receptacle and mouthpiece aperture aligned, is oriented 90 degrees from the mouthpiece, and connected only by pivot (34/64) to the lower body portion of the device. If the mouthpiece was rotated to reside behind the mouthpiece, the device lacks any suitable mechanism to keep the mouthpiece in place. Yet even if a detent was provided which frictionally held the back wall of the main body portion, it would not nest so as to encapsulate "a substantial portion of the second part", as claimed in claim 1.

It is also respectfully asserted that claim 1 is not obvious over Dmitrovic because one of ordinary skill would not be motivated to make such a change such that the mouthpiece cover would be engaged behind the main body in a nesting fashion, as it would tend to increase the instance of patient misuse. Specifically, the Dmitrovic device operates to meter a dose of

material into the metering recess from a reservoir while the device is in the closed orientation, with the mouthpiece cover covering the mouthpiece. As described in Dmitrovic, the mouthpiece cover, in the open position, being oriented at 90 degrees to the mouthpiece, rotated on pivot (34/64) and not connected to the main body, acts as a reminder to patient to carry out the return rotation stroke of the cover to its closed orientation. This allows the cover to keep unwanted material from the mouthpiece, and permits the metering recess to communicate with the reservoir to be refilled.

One of ordinary skill would realize that such a reminder is important in complying with proper device usage. If constructed as suggested by the examiner, modified in some fashion to hold the cover against the back of the device, the device could be, as the examiner describes it, a "compact and easy to hold container" but also one that does nothing to act as a reminder to reset the mouthpiece cover in the closed orientation both to prevent soiling of the mouthpiece and assure refilling of the metering receptacle.

Applicants also disagree with the examiner's position that it would have been obvious to modify the mouthpiece cover such that a substantial portion of the main body would nest within the mouthpiece. Applicants fail to see how this would occur while employing the pivotal attachment (34/64) at the bottom of the mouthpiece cover. The main body behind the mouthpiece is depicted as being straight. No portion of the back of the main body projects in such a way as it could be engaged by the mouthpiece, let alone nest within the mouthpiece. As such, there is no manner in which the internal cavity of the mouthpiece cover would encapsulate a substantial portion of the main body when moved behind the main body.

If, solely for the sake of argument, one assumes that attachment of the mouthpiece to the main body was to occur while the Dmitrovic device is in the open position, it would likely be accomplished employing the same mechanism used to keep the cover engaged with the main body when in the closed position. The mechanism by which the cover is held to the main body in the closed position is not mentioned in the text. The examiner's reference to air inlet grill (80) does not serve such a function. Figure 6, however, shows the main body as having a small ridge above the mouthpiece which engages a corresponding detent on the top interior portion of the mouthpiece cover when the device rests in its closed position. Taking the

examiner's approach that one would want to hold the cover against the main body in the open position to make a "compact device", one would assume that a similarly constructed ridge would be placed on the back wall of the main body, and that the mouthpiece if rotated 180 degrees as suggested by the examiner, would engage such a ridge. However, even in this position, the cover would not nest the main body, nor would it encapsulate a substantial portion of the main body. While the examiner relies resources beyond specification- i.e., a dictionary to replace the words of the claims, applicants believe that the context of the specification and the drawings would indicate that "substantial portion" would not be read in such a skewed manner as to say that connection to a small ridge on the back of the main body, without encapsulating any other portion of the main body, falls within the meaning of the "encapsulating a substantial portion of the second part" as set out in claim 1. It is asserted that this claim language is readily understandable to those of ordinary skill, and that Dmitrovic does not describe or render obvious this feature of Claim 1, let alone the claim as a whole.

Each of the claims directly or indirectly dependent from Claim 1, i.e., claims 2-10, 14-33 and 36-39 are patentable over Dmitrovic for the same reasons as Claim 1 is patentable, as described above.

Claim 40 is also independent. Claim 40 recites that the device in an open, first angular position, the first part is "disposed behind the second part", and that in the first angular position the first and second parts "nest together", and wherein, in the nesting state the first and second parts form an "interference fit" to releasably fastened together.

As explained in detail above, Dmitrovic does not suggest or describe a device where the mouthpiece cover is rotatable behind the main body portion of the device, or one where the mouthpiece cover nests the main body portion, nor one where the mouthpiece cover and main body portion form an "interference fit." For the reasons detailed above one of ordinary skill would be directed away from making modifications Dmitrovic in the manner of the claimed invention. Like Claim 1, claim 40 is both novel and non-obvious over the art relied on by the examiner in the action.

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Each of the claims directly or indirectly dependent from Claim 40, i.e., claims 41-44 are patentable over Dmitrovic for the same reasons as Claim 40, as described above.

Applicant respectfully requests withdrawal of all rejections and allowance of the claims now pending.

To the extent that applicant's have not addressed specific points made by the examiner to the dependent claims, or additional points raised to the independent claims, this is done without prejudice and should not be taken as admission to the propriety of the examiner's position. The applicant reserves the right to address any such points should the need arise in the future.

**Conclusion**

Applicants request reconsideration of the application. It is believed that the response places the application in a condition for allowance, and a Notice Of Allowance is respectfully requested. If any minor points precluding a Notie of Allowance exist, the examiner is requested to contact the applicant's agent at the number listed below.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge any fees or credit any overpayment, particularly including any fees required under 37 CFR Sect 1.16 or 1.17, and any necessary extension of time fees, to deposit Account No. 07-1392. The Examiner is invited to contact the undersigned at (919) 483-9995, to discuss this case, if desired.

Respectfully submitted,

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